

**REMARKS**

Reconsideration of the subject application is respectfully requested.

Claims 1-2 and 5-20 are pending in the present application. Claims 1, 7, 9-12, 16, and 18-20 are being amended in the present amendment.

The present invention is directed to a method and apparatus for determining the effectiveness of a patient's therapy by capturing data regarding the patient's therapy, storing data on other therapy procedures, presenting a display of the patient's therapy particularly related to the patient's body-mass index, and determining the effectiveness of the patient's therapy relative to the other therapies.

The Examiner rejected claims 8-12 and 17-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claim 12 is being amended in part to include a colon following the word "comprising". In addition, claims 7 and 16 are being amended to include the words "extremely obese". With regard to the rejection of claims 8-11 and 17-20 and the question of what occurs to a person with a BMI of 24.5, for example, the claims do not include such an intermediate BMI. Nevertheless, the lack of including such an intermediate BMI does not cause the claims, each of which includes a specific range, to become unpatentable.

With regard to the Examiner's Note on Nonfunctional Descriptive Material, the Examiner appears to have repeated the comments made in an earlier Office

Action without indicating any new statutory ground for rejection. In the previous Office Action, claims 1 and 2 were rejected under 35 U.S.C. § 101 for the lack of a positively recited step, and claim 1 was also rejected under 35 U.S.C. § 112, paragraph 2, as being indefinite. The Applicants disagree that the data stored and displayed are not material. It is precisely because the data are used for analysis purposes that the data are material and, in particular, visually displaying a relationship between BMI data and CPAP therapy is novel and provides a useful function. Further, the calculation of the graph of the display is a function of the computer and the display is pertinent to the data. In the present Office Action, claims 1 and 2 are not described as being rejected under either 35 U.S.C. § 101 or 35 U.S.C. § 112, paragraph 2. It remains unclear whether either or both of those rejections remains pending. Regardless, for reasons described below, independent claims 1 and 12 are being amended to include a step or function for storing representative treatment results regarding a plurality of patients and analysis/comparison of the representative results to treatment results of a patient so as to determine the relative effectiveness of sleep disordered breathing management of the patient.

In the present Office Action, claims 1, 2, 12, and 13 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent Publication 2003/0208465 to Yurko ("Yurko"). Claims 5, 6, 14, and 15 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Yurko in view of U.S. Patent No. 7,039,458 to Ueda ("Ueda"). Claims 7 and 16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Yurko in view of Ueda and the article "Trends" (Cynthia L

Leibson, David F Williamson, L Joseph Melton III, Pasquale J Palumbo, et al.  
"Temporal Trends in BMI Among Adults With Diabetes". Diabetes Care.  
Alexandria: Sep 2001, Vol. 24, Iss. 9; p.1584).

Claims 1 and 12, as presently amended, each includes one or more limitation which are not disclosed or suggested by Yurko, Ueda, or Trends. All of the claims include a limitation of a display and a limitation specifically directed to a computer ascertaining relationships and trends and comparing these results to results of other treatment methodology. These limitations are not disclosed or suggested anywhere in the cited references. In addition, there is no suggestion in any of the references to combine with any or all of the other cited references.

The present invention is directed, in part, to amassing treatment data of a patient, determining its effectiveness, and comparing the effectiveness to other treatment methodologies. Yurko is directed to a different invention. Yurko is directed to "three basic sub-systems or categories, namely, input, modification and presentation." (Yurko ¶ 0030). With regard to Yurko's input, Yurko discloses obtaining patient and compliance data, which is calculated and potentially uploaded (see Yurko ¶ 0034). Yurko is not directed to analyzing the data, collecting the specific types of data collected and analyzed in the present invention, or anything related to displaying data to depict a relationship between metrics. Also, Yurko is not directed to comparing treatment results. Yurko does not disclose or suggest anything with respect to comparisons among different treatment approaches or comparisons of treatments between patients. Further, Yurko does not disclose or suggest any display or anything related to BMI.

With regard to the rejection of dependent claims 5-6 and 14-15, the Examiner relies on Ueda for disclosing use of BMI data to characterize a patient based on predetermined BMI ranges. However, Ueda is directed to measuring body fat, which is something completely unrelated to the present invention, which is directed to respiration therapy effectiveness. In the present invention, a BMI measurement is used, and its characterization is achieved for display purposes, but its use is unrelated to the disclosure of Ueda. Further, there is no suggestion to combine Ueda with Yurko.

With regard to the rejections of claims 7 and 16, the Examiner relies in part on Ueda for the same reasons as described above and in part on Trends for teaching BMI categorizations. However, Trends is directed to treatment of diabetic patients, which is something completely unrelated to the present invention, which is directed to respiration therapy effectiveness. Further, there is no suggestion in any of Yurko, Ueda, or Trends to combine references.

The early passage to issue of the application is respectfully requested.

Respectfully submitted,  
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